2018 Current Fiscal Year Report: Pharmaceutical Science and Clinical Pharmacology Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	878

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	01/22/2018	01/22/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 0 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$4,167.00	$8,750.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$155,541.00	$157,943.00
18a(4). Personnel Pmts to Non-Member Consultants	$1,572.00	$2,734.00
18b(1). Travel and Per Diem to Non-Federal Members	$7,450.00	$11,963.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$1,108.00	$1,854.00

18c. Other(rents,user charges, graphics, printing, mail, etc.)	$41,485.00	$42,112.00
18d. Total	$211,323.00	$225,356.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The Committee shall provide advice on scientific, clinical and technical issues related to safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have and as required, any other product for which the Food and Drug Administration has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are selected from academic, research and practice settings and include researchers knowledgeable in the fields of biostatistics, bioavailability, clinical pharmacology, pharmacokinetics, pharmaceutics, industrial pharmacy, statistics, biopharmaceutics, and other related professions. The committee included one technically qualified voting member who is identified with consumer interests. The committee may also include four non-voting members who are identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?

The committee met one time during FY-18. On September 20, 2018, the committee discussed two topics that related to the Office of Pharmaceutical Quality's priority of promoting the availability of better medicine. During the morning session, the committee discussed the modernization of assessing drug applications through a Knowledge-aided Assessment and Structured Application (KASA) initiative. During the afternoon session, the committee discussed in-vitro in-vivo relationship (IVIVR) standards and sought input on establishing patient-focused dissolution standards for oral solid modified-release dosage forms. Regarding the KASA initiative, the committee voted in the affirmative (10 Yes – 0 No – 0 Abstain) that FDA should consider enhancement of submission format to improve the efficiency and consistency of regulatory quality assessment. Several members stated that this would increase communication while making submissions from industry easier and more transparent. When asked to vote on if FDA should establish patient-focused dissolution standards for extended-release solid oral dosage forms, the committee also voted in the affirmative (11 Yes – 0 No – 0 Abstain). Several members agreed that this would advance pharmaceutical science, improve drug and quality standards, and increase our understanding of extended-release dosage forms by adding to the body of information to help patients. It is expected that the committee will meeting twice during FY-19.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the committee are drawn from academia, research, and/or clinical practice. Their advice and input lends credibility to regulatory decisions made and helps those decisions stand up to intense public scrutiny. The alternate means of obtaining this advice would be to hire large numbers of scientists on a full time basis at great expense to the government.

20e. Why is it necessary to close and/or partially closed committee meetings?

The committee held no closed meetings during FY-18.

21. Remarks

This committee was not required to do any reporting for FY-18.

Designated Federal Officer

Jay R. Fajiculay DFO

Committee Members	Start	End	Occupation	Member Designation
Amidon, Gregory	09/22/2015	10/31/2019	Research Director of Pharmaceutical Sciences College of Pharmacy, Department of Pharmaceutical Sciences, Director of Pharmaceutical Engineering, University of Michigan	Special Government Employee (SGE) Member
Awni, Walid	04/21/2016	10/31/2019	Vice President, Clinical Pharmacology and Pharmacometrics, AbbVie	Representative Member
Carrico, Jeffery	12/30/2015	10/31/2022	Service Chief, Clinical Pharmacy and Investigational Drug Research, National Institutes of Health	Regular Government Employee (RGE) Member
Cloyd, James	11/01/2013	10/31/2017	Director, Center for Orphan Drug Research and Professor, Dept of Experimental and Clincial Pharmacology, University of Minnesota	Special Government Employee (SGE) Member
Cook, Jack	04/21/2016	10/31/2019	Vice President, Clinical Pharmacology, Global Product Development, Pfizer	Representative Member
Donovan, Maureen	09/27/2018	10/31/2020	Professor of Pharmaceutical and Translational Therapeutics, University of Iowa College of Pharmacy	Special Government Employee (SGE) Member
Finestone, Sandra	11/01/2017	10/30/2021	Consumer Representative; Executive Director, Association of Cancer Patient Educators	Special Government Employee (SGE) Member
Li, Tonglei	09/19/2016	10/31/2020	Allen Chao Chair and Professor of Industrial and Physical Pharmacy, Purdue University, School of Pharmacy	Special Government Employee (SGE) Member

Mager, Donald	12/30/2014	10/31/2018	Professor and Vice Chair of Pharmaceutical Sciences, University of Buffalo, SUNY	Special Government Employee (SGE) Member
Neville, Kathleen	11/01/2013	10/31/2017	Professor of Pediatrics, University of Arkansas for Medical Sciences	Special Government Employee (SGE) Member
Richmond, Frances	09/27/2018	10/31/2021	Professor and Chair, Department of Regulatory Chair and Quality Sciences, USC College of Pharmamcy	Special Government Employee (SGE) Member
Robinson, Anne	11/01/2013	10/31/2017	Chair and Catherine and Henry Boh Professor of Engineering, Tulane University	Special Government Employee (SGE) Member
Slattum, Patricia	09/19/2016	10/31/2018	Professor of Pharmacotherapy and Outcomes Science, Virginia Commonwealth University, School of Pharmacy	Special Government Employee (SGE) Member
Smith, Paul	09/27/2018	10/31/2021	Associate Professor of Statistics, University of Maryland	Special Government Employee (SGE) Member
Sun, Duxin	09/19/2016	10/31/2019	Professor, University of Michigan, College of Pharmacy	Special Government Employee (SGE) Member
Tenjarla, Srini	04/21/2016	10/31/2019	Vice President and Head of Global Pharmaceutical Sciences, Shire	Representative Member
Terzic, Andre	09/29/2017	10/31/2020	Marriott Family Professor in Cardiovascular Diseases, Mayo Clinic	Special Government Employee (SGE) Member
Waldman, Scott	12/30/2014	10/31/2018	Chairman and Professor Departments of Pharmacology and Experimental Therapeutics and Medicine, Thomas Jefferson University	Special Government Employee (SGE) Member

Number of Committee Members Listed: 18

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Pharmaceutical Science and Clinical Pharmacology Advisory Committee supports FDA's strategic priorities by reviewing and

evaluating data on scientific and technical issues concerning the safety, and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases, and as required, any other product for which the Food and Drug Administration has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's generic drug regulatory responsibilities. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

The utilization of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee enabled the Agency to obtain required and frequently scarce services from medical and scientific experts not otherwise available to the Agency; and to obtain the services from these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
144

Number of Recommendations Comments
The committee made 144 recommendations from FY-03 through the first half of FY-18. See question 20a of the annual report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
80%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
10%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	✓
Reallocated resources	
Issued new regulation	✓
Proposed legislation	
Approved grants or other payments	
Other	✓

Action Comments

FDA approves or chooses not to approve an investigational new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

N/A